

REMARKS

I. Prosecution History

A preliminary amendment canceling claims 1-12, 16, 18-39, 46-48 and 51-63, and adding new claims 64-69 was co-filed with the application. Claims 15, 17, 42-45 and 65-69 were canceled and new claims 70-73 were added in the amendment filed in response to the Office action mailed June 20, 2006.

Claims 13, 14, 40, 41, 49, 50, 64 and 70, 72 and 73 are pending and under examination, with all of these claims except claims 13, 14 and 64 at issue in the Office Action. Claim 71 is canceled. Claim 13, 14 and 64 stand allowed.

II. The rejection under 35 U.S.C. § 112, first paragraph (written description), should be withdrawn.

The Examiner rejected claims 40, 41, 49, 50 and 70-73 under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Applicant requests reconsideration of the rejection in view of the amendments made herein and the following remarks.

As amended, claim 70 (from which claims 40, 41, 49, 50, 72 and 73 depend) is drawn to an isolated polypeptide comprising an amino acid sequence at least 95% identical to the amino acid sequence set forth in SEQ ID NOs: 8 or 10, wherein said polypeptide is capable of binding TRAIL. Descriptive support for the percent identity can be found, for example, on page 8, lines 4-5.

The written description training materials speak approvingly of the use of percent identity to claim biological inventions. The most relevant example from the training materials, Example 14, pertains to a claim to a hypothetical genus of proteins embracing both a specific amino acid sequence and “variants” having a defined sequence similarity, so long as the variants retain a specified activity of the protein. In the hypothetical example, the specification discloses only a single species of protein falling within the claim, but the specification also provides an assay for identifying all of the variants which are capable of exhibiting the specified activity. Even though the hypothetical specification in Example 14 contained only a “single disclosed species,” the Patent Office concluded that the genus claim was adequately described and stated, “[o]ne of skill in the art would conclude that Applicant was in possession of the necessary common attributes possessed by the members of the genus.”

The “necessary common attributes” of claim 70 are analogous to Example 14 of the Written Description Guideline training materials, insofar as the polypeptide recited in claim 70 is an isolated polypeptide capable of binding TRAIL, and the variants that are embraced within the claim also are required to retain that property (i.e., capability of binding TRAIL). As in Example 14 of the training materials, the application teaches a routine screening assay to identify polypeptides that bind TRAIL. (See Example 9 of the specification.) Guided by Example 14 of the training materials, Applicant submits that the polypeptide recited claim 70 is adequately described. The present specification expressly describes the polypeptide species comprising the amino acid sequences set forth in SEQ ID NOs: 8 and 10. Moreover, all of the variants must possess the specified activity (i.e., capability of binding TRAIL) and must have at least 95% structural identity with the amino acid sequence set forth in SEQ ID NO: 8 or SEQ ID NO: 10.

In view of the foregoing, Applicant respectfully submits that the claimed genus is adequately described in the specification and the rejection of claim 70 under 35 U.S.C. § 112, first paragraph (written description), should be withdrawn.

III. The rejection under 35 U.S.C. § 112, first paragraph (enablement), should be withdrawn.

The Examiner rejected claims 40, 41, 49, 50 and 70-73 under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Applicant requests reconsideration of the rejection in view of the amendments made herein and the following remarks.

As discussed above in Section II, the specification adequately describes polypeptides comprising an amino acid sequence that is at least 95% identical to either of the amino acid sequences set forth in SEQ ID NOs: 8 and 10, wherein said polypeptide is capable of binding TRAIL. The application further describes a routine screening assay to identify polypeptides that bind TRAIL. In view of the disclosure of relevant primary structures (i.e., sequences) and the disclosure of routine screening assays to identify polypeptides capable of binding TRAIL, the application-as-filed teaches one of skill in the art how to make and use an isolated polypeptide comprising an amino acid sequence encoded by a nucleic acid sequence set forth in SEQ ID NOs: 7 or 9 or an amino acid sequence that is at least 95% identical to an amino acid sequence set forth in SEQ ID NOS: 8 or 10, wherein the polypeptide is capable of binding TRAIL. Accordingly, claim 70 (and those claims dependent therefrom) is fully enabled by the specification.

IV. The rejections under 35 U.S.C. §112, second paragraph, should be withdrawn.

The Examiner rejected claims 40, 41 and 49 as being indefinite for improper claim dependencies. In response, claims 40 and 49 have been amended to recite, "isolated polypeptide of any one of claims 13, 14, and 70-73." Claims 40 and 49 now properly depend from claims presented in the current claim set. Due to the amendment of claim 40, claim 41 is now in proper form. Accordingly, the rejection should be withdrawn.

V. Double Patenting Rejection

The Examiner maintained the rejection of claims 49 and 50 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 18 of U.S. Patent No. 6,627,199. Applicant requests that the Examiner hold the double-patenting rejection in abeyance until such a time as the remaining issues have been addressed. At that point Applicant will consider filing a terminal disclaimer.

VI. Conclusion

It is believed that the foregoing amendments and remarks respond to all of the objections and rejections found in the Office Action. If the Examiner believes that a telephone conversation would expedite allowance of the claims, she is invited to contact the undersigned agent or William K. Merkel, Attorney for Applicant, at the number indicated below. The Director is hereby authorized to charge any additional fees required with the filing of this paper to Deposit Account No. 13-2855, under Order No. 01017/35434B.

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Respectfully submitted,

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